Stago

K092113

Attachment – 4

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Umberto V. Parrotta
Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

NOV 13 2009

Phone: (973) 631-1200, x-2044
Facsimile: (973) 695-0095

Contact Person: Umberto V. Parrotta

Date Prepared: July 10, 2009

Name of Device and Name/Address of Sponsor:

STA® - Free PS Calibrator

Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Common or Usual Name:

- Secondary Calibrator.
- IVD Calibrator.
- IVD Coagulation Calibration Device.

Classification Name:

- Calibrator, Secondary.

Predicate Device:

- HemosIL™ (K041905).

Purpose of the Traditional 510(k) Notice:

- The STA® - Free PS Calibrator is a new calibration kit for Free Protein S assays using the STA® product line of IVD analyzers (STA-R® and STA Compact®).

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510(k) SUMMARY

Indication/Intended Use:

STA® - Free PS Calibrator kit is a set of calibrator plasmas intended for use with analyzers of the STA® line suitable to these reagents for the calibration of free protein S assays by the immuno-turbidimetric method, STA® - Liatest® Free PS.

Technological Characteristics:

The STA® - Free PS Calibrator kit is a set of lyophilized human plasmas used to create the calibration curve on an IVD instrument performing the immuno-turbidimetric method for free protein S assays, STA® - Liatest® Free PS. Such IVD instruments being the STA® product line of medical device analyzers such as STA-R® and STA Compact®.

In the lyophilized state and uncompromised primary packaging, the product calibrator plasmas remain stable for a period of 18 months from the date of manufacture when stored at 2 – 8°C. In the reconstituted state, STA® - Free PS Calibrator have demonstrated to be stable for 4 hours on board STA-R® and STA Compact®.

Substantial Equivalence:

The product, STA® - Free PS Calibrator and the predicate device, HemosIL™ Calibration plasma are similar in indication/intended use, technology, principles of operation, and application of use (with IVD medical device analyzers) thus yielding no new questions in safety, effectiveness, or technology. In addition, performance data enclosed in this notice further demonstrates suitability for the intended use. Therefore, this concludes the product STA® Free PS Calibrator is substantially equivalent to the predicate device, HemosIL™ Calibration plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Diagnostica Stago, Inc.
c/o Mr. Umberto V. Parrotta
Director of Regulatory Affairs and Quality Assurance
5 Century Drive
Parsippany, NJ 07054

NOV 13 2009

Re: k092113
Trade/Device Name: STA – Free PS Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: October 8, 2009
Received: October 9, 2009

Dear Mr. Parrotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Attachment – 1

Indications for Use

510(k) Number (if known): K092113

Device Name:

STA® - Free PS Calibrator Kit

Indications for Use:

STA® - Free PS Calibrator kit is a set of calibrator plasmas intended for use with analyzers of the STA® line suitable to these reagents for the calibration of free protein S assays by the immuno-turbidimetric method, STA® - Liatest® Free PS.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k092113